

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

In re Patent Application of:

Christopher J. D. POMFRETT, et al.

Atty. Ref.: LSN-39-314

Serial No.: 10/553,745

Art Unit: 3736 - Conf. No.: 6133

Filed: October 18, 2005

Examiner: Michael C. Stout

For: NERVOUS SYSTEM MONITORING METHOD

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

SECOND DR. POMFRETT DECLARATION UNDER 37 C.F.R. §1.132

I, Dr. Christopher John Douglas Pomfrett, do hereby declare and state as follows:

1. I am a clinical scientist and a lecturer in Neurophysiology applied to anaesthesia at the University of Manchester in the United Kingdom. I obtained a BSc degree in Comparative Physiology with Zoology from Queen Mary College, London University, with first-class honors in 1983. I went on to undertake post-graduate research in the field of neurophysiology at The Medical College of St. Bartholomew's Hospital, London, where I was awarded the degree of doctor of philosophy. I have twenty-two years of post-doctoral experience in physiological measurement, including experience of electroencephalography (EEG), electrocardiology (ECG) and other devices used to measure patients in the operating room. I am also experienced in intracellular and extracellular neurophysiology.

2. I am a co-inventor of the inventions claimed in U.S. patent application Serial No. 10/553,745 ("the Application"). I am, therefore, fully familiar with the

Application. I have read the office action issued by the U.S. Patent and Trademark Office on June 22, 2010, and have now considered the John '372 document that is newly cited therein.

3. My first Declaration Under 37 C.F.R. §1.132 executed October 26, 2009 (and filed in the USPTO on October 30, 2009), is hereby incorporated by reference *vis-à-vis* earlier cited documents.

4. Pending claims that require a set of voltage measurements to be collected from a predetermined measurement period that begins after a predetermined delay based upon a neurological model following occurrence of a sensory stimulus are not taught or suggested in any of the cited prior art – e.g., John '372, John '335 and/or Boone '142 documents now relied upon by the Examiner.

5. The Examiner indicates that John '372 teaches a method of monitoring a brain stimulus response during a predetermined measurement period initiated after a predetermined delay following the stimulus based upon a neurological model.

6. However, as described paragraph [0016], John '372 is concerned with analyzing depth of anesthesia. A first set of reference, or self-norm, measurements is obtained after the patient has been placed into a desired depth of anesthesia, as determined by a clinical anesthesiologist using his/her clinical judgment. During an operation, a "QEEG system automatically and continually collects on-going EEG" while applying stimuli to the patient (John '372, page 2, right-hand side, lines 3-5). Features from the self-norm data are continuously analyzed and displayed as trajectories.

7. John '372, therefore, teaches that EEG data is continually collected and analyzed. That is, John '372 cannot be said to extract voltage measurements for analysis over a predetermined period that begins after a predetermined delay based upon a neurological model. This continuous collection and analyzing of data is

emphasized throughout John '372 by reference to the display of output data as trajectories indicating display of continuous measurements and reference to quantitative features being continuously extracted and analyzed from on-going EEG data (John '372, page 3, left-hand side, lines 29-30). As such, the skilled person learns from John '372 that EEG data is continuously measured and continuously analyzed with respect to reference measurements.

8. The Examiner refers to paragraph [0034] of John '372 and appears to indicate that paragraph [0034] teaches an evoked signal obtained after a delay selected based upon a neurophysiologic model. However, given the clear teaching of John '372 that EEG data is collected and processed continually, this cannot be correct.

9. There is nothing in paragraph [0034] of John '372 to teach or suggest that the signals obtained by the multiplexer are based upon a delay selected based upon a neurological model.

10. As previously noted at paragraphs 23 and 24 of my earlier Declaration, EEG measurements are generally concerned with average measurements providing an indication of a general response to stimulus, rather than a specific response of a part of the brain that is active at a specific time after application of a stimulus. As such, processing of measurements obtained at a particular time delay after stimulation using an EEG system simply does not make sense given the necessary averaging of a plurality of measurements over a period of time when using an EEG system.

11. Paragraph [0034] of John '372 is clear that measurements are applied during stimulation while a number of stimuli are applied, and paragraph [0035] of John '372 is also clear that the obtained measurements, or "Evoked Potentials", are averaged to reduce noise.

12. Paragraphs [0034]-[0035] of John '372 are clear that John '372 is concerned with a general response indicative of general brain activity while a stimulus is being applied. This clearly teaches away from the specific brain response obtained using voltage measurements collected from a predetermined measurement period that begins after a predetermined delay based upon a neurological model following occurrence of a sensory stimulus, as required by each of claims 22, 38 and 42.

13. Not only does John '372 lack any teaching or suggestion of the claim requirement for obtaining a specific brain response collected over a predetermined measurement period that begins after a predetermined delay based upon a neurological model following occurrence of a sensory stimulus – the same deficiency is shared by all the other cited prior art if taken in the various asserted combinations with John '372.

14. The general response to stimulus of John '372, obtained by continuously measuring during stimulation and by continuously averaging a large number of such responses, is clearly very different from the specific brain response harvested at a particular input time delay as claimed.

15. The attached graphical data was obtained using a system that is capable of monitoring delayed responses from different brain areas. The ECG-labelled trace is not of particular relevance; however, the other traces indicate application of a stimulus (trace labelled "Stim") and responses to the stimulus obtained using different pairs of electrodes positioned at different spatial locations on a patient's head (traces thereabove). The traces showing responses to the stimulus clearly show responses occurring at different times in different parts of the brain. The responses are consistent with a neurological model such that selecting a delayed signal capture/analysis period based upon the model can provide clinically useful information. The attached data only demonstrates that a specific response of a part of the brain can be identified at a particular time after stimulus application using the

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EIT system. In this experiment, data was continuously collected and not isolated with respect to a particular time-delayed period as claimed. That is, the attached data merely illustrates a factual basis underlying the claimed invention and does not, *per se*, illustrate the complete invention as claimed (e.g., collected data from a particular delayed interval was not extracted from the continuously acquired data and analyzed).

16. I hereby declare that all statements made herein of my own knowledge are true and that statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Signed this 126 day of DECEMBER, 2010.

Respectfully submitted,

By:



Christopher John Douglas Pomfrett

